

REMARKS

Reconsideration of the present application is respectfully requested.

Claims 5-12 have been canceled and new claims 13-24 have been added to the application. Support for the new claims can be found throughout the specification, such as for example on page 13, the paragraph beginning at line 19 and test examples 1 and 2 on pages 16-18.

Claims 1-12 have been rejected under 35 U.S.C. 102(b) as being anticipated by the European Patent No. 1 318 201 A1 ("EP201"). The Examiner has argued that EP201 on page 2 discloses the claimed pharmaceutical compositions comprising anthocyanin.

This rejection is respectfully traversed for the following reasons.

The Examiner has incorrectly characterized the reference as disclosing pharmaceutical compositions. EP201 is directed solely to a method of preparing purified anthocyanidin glucoside compounds and fails to disclose pharmaceutical preparations of that anthocyanidin. Further, the reference also does not disclose activities of anthocyanidin claimed in the present invention. Page 2, paragraph [007] of EP201 states that "*Conventionally, anthocyanin compositions for pharmaceuticals are mainly preparations derived from blueberry. . .*". Paragraphs [008]-[012] of the reference continue to summarize difficulties in the preparation of anthocyanin compounds. EP201 goes on to disclose a method of producing purified anthocyanin from natural sources and a method of producing crystalline anthocyanin from the purified anthocyanin, but fails to disclose any activities of the production of purified anthocyanidin glucoside.

EP201 does not disclose activities of anthocyanidin as recited in the present claims; namely, an inhibitor of the formation of advanced glycation end products and an inhibitor of aldose reductase. There is no teaching or suggestion in the EP201 reference that purified anthocyanidin glucoside has the activities of inhibiting the formation of advanced glycation end products or inhibiting aldose reductase. Further, EP201 contains no teaching or suggestion of preventing or treating disease caused by the formation of advanced glycation end products or aldose reductase activity by administering an inhibitor. The inhibitor of the formation of advanced glycation end products or the inhibitor of aldose reductase comprising anthocyanin of the present invention are useful as preventative and therapeutic agents against the peripheral effects of diabetes or galactosemia based on preventative and therapeutic action against diabetic complications related to AGE formation or against other various disease relating to AGE formation and aldose-reductase-inhibiting action.

It is well established in the case law that if a limitation in the preamble of a claim necessarily gives meaning to the claims and properly defines the invention, then such limitation must be considered when determining the patentability of the claims. The predecessor court of the Court of Appeals for the Federal Circuit (CAFC), namely, the Court of Customs and Patent Appeals (CCPA), summarized this approach in *Kropa V. Robie*, 88 USPQ 478(1951), after reviewing some 37 cases that turned on the limiting nature of the preambles to the claims in suit. See also *Loctite Corp v. Ultraseal Ltd.*, 228 USPQ 90, 94 (Fed. Cir. 1985). According to the court in *Kropa*:

[T]he preamble has been denied the effect of a limitation where ... the claim or [interference] count apart from the introductory clause completely defined the subject matter [of the invention], and the preamble merely stated a purpose or intended use of that subject matter. On the other hand, in those... cases where the preamble to the claim or count was expressly or by necessary implication given the effect of a limitation, the introductory phrase was deemed essential to point out the invention defined by the claim or count. In the latter class of cases, the preamble was considered necessary to give life, meaning and vitality to the claims or counts.

Examples of preambles cited in *Kropa* as expressly or impliedly helping to express a limitation in the claims were “An insecticide” and “An insecticide composition.”

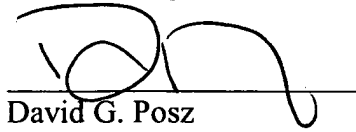
Applicant respectfully submits that the claims in this application present precisely the situation where the preamble of a claim was held to express a limitation in the claim in *Kropa*. The preamble of applicant’s claims distinguishes the presently claimed invention by defining inhibitory activity such as inhibiting the formation of advanced glycation end products and inhibiting aldose reductase, with the inhibitor comprising anthocyanin. Therefore, applicant respectfully submits that the teachings of EP201 are not concerned with the inhibition of the formation of advanced glycation end products or inhibition of aldose reductase and therefore provide no reason for one of ordinary skill in the art to the presently claimed inhibitors or methods of use thereof.

As EP201 clearly fails to teach or disclose all features of the inhibitors or methods of the present invention, the Examiner has failed to establish a *prima facie* case of anticipation. Therefore, it is respectfully requested that the rejection of claims 1-4 be withdrawn. EP201 also fails to teach or suggest the claimed invention of new claims 13-24 which describe a method of treating or preventing disease by administering a pharmaceutical composition comprising an inhibitor of the formation of advanced glycation end products or an inhibitor of aldose reductase.

In view of the foregoing, applicants respectfully submits that this application is in condition for allowance. A timely notice to that effect is respectfully requested.

Please charge any unforeseen fees that may be due to Deposit Account No. 50-1147.

Respectfully submitted,



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